



Spectrum Health

Butterworth Campus

100 MICHIGAN STREET NE GRAND RAPIDS MI 49503-2560
616 391 1774 FAX 391 2745 www.spectrum-health.org

January 31, 2006

Norma Hagenow, Chair
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building
201 Townsend Street
Lansing, Michigan 48913

Dear Ms. Hagenow,

This letter is written as formal testimony about the CON Review Standards for Bone Marrow Transplant, which went into effect on September 21, 2005. Spectrum Health appreciates the opportunity to comment on these Standards. Following are two (2) areas of comment: clinical applications of BMT and specific revisions to the standards.

Clinical Applications

Since the substance of these Standards was developed in 1997, clinical applications of bone marrow transplantation (BMT) for adult cancer patients have continued, and the number of new cancer cases has increased. Currently, the following common adult cancer conditions represent indications for BMT:

For Allogeneic Transplantation

- Initial treatment of poor prognosis Acute Myelogenous Leukemia (AML) and at first relapse in other AML subsets;
- Curative treatment of Myelodysplastic Syndrome (MDS) presenting in younger age groups (<60 yrs old).
- Curative treatment of Acute Lymphoblastic Leukemia in younger age groups;
- Non-Hodgkins Lymphoma patients in relapse; and
- Treatment of younger patients with Multiple myeloma.

For Autologous Transplantation

- Treatment of younger patients with relapsed intermediate or high grade Non-Hodgkins Lymphoma;
- Initial treatment of younger patients (<60 yr) with Multiple Myeloma;
- Treatment of younger patients with relapsed Hodgkins Disease; and
- Treatment of relapsed Testicular Cancer in younger patients.

Proposed Revisions

In light of the expansion in the application of BMT, including stem cell replacement therapy, the existing restriction of three (3) adult BMT programs statewide is unreasonable. As the state's population ages, with the corresponding increase in the incidence of cancer, three (3) adult BMT sites in the state represent inadequate availability of this important cancer treatment modality. Furthermore, for residents of the western part of the state, all three full-service BMT programs are located in southeastern Michigan, at least 120 miles away. In West Michigan, one Grand Rapids medical oncology group annually diagnoses more than forty (40) adult patients with the clinical conditions described above. These patients must be referred out of the area for BMT procedures. Such referrals require uprooting families for long periods of time (about 3 months) for the initial treatment alone. Furthermore, successful BMT patients may need to return to the transplant center for regular follow-up, possibly for the remainder of their life. Unavailability of this potentially curative treatment in West Michigan deprives many patients of life-saving therapy, as they may be unable to be relocated for long periods of time. For these reasons, the availability of BMT programs should be improved statewide, both in terms of number of programs and also in terms of geographic location.

Additional aspects of the Standards need to be reviewed. Of particular concern are the minimum volume requirements. In general, the minimum volumes contained in the CON Standards are consistent with accreditation standards developed by the Foundation for the Accreditation of Cellular Therapy (FACT) and the Joint Accreditation Committee ISCT EBMT (JACIE), now in their second edition. This is true for the standards applicable to programs performing only allogeneic transplants and for those performing both allogeneic and autologous transplants. However, the CON requirement (10 transplants per year) for a program performing only autologous transplants is greater than the requirement (5 transplants per year) contained in the proposed 3rd edition of the FACT-JACIE accreditation standards. The state requirements should not be more stringent than the FACT-JACIE requirements. Upon finalization of the 3rd edition of the FACT-JACIE accreditation standards, the CON Review Standards should be revised to be consistent with them.

In Section 3 of the CON Standards, there is no discussion of a combined adult and pediatric BMT program. The implication is that such programs represent two (2) separate entities, each of which must meet separate volume requirements (i.e., 10 annually for the adult service, and 10 annually for the pediatric service). The 2nd edition FACT standards specifically address combined adult and pediatric programs and require an annual volume of four (4) adult patients and four (4) pediatric patients. The proposed 3rd edition FACT-JACIE standards will require five (5) from each patient population. The CON requirements should acknowledge combined adult and pediatric BMT programs and adjust the minimum volume requirements to match the FACT-JACIE standards.

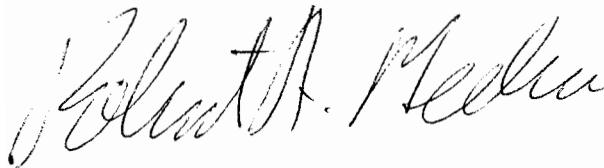
Also in Section 3 is a description of the characteristics of an “existing bone marrow transplantation service,” with which a proposed new BMT program must enter into a “consulting agreement.” The minimum volume requirements for the existing program are excessively high and far exceed any applicable accreditation standards. Patient volumes consistent with FACT-JACIE accreditation requirements should be sufficient for an existing program to provide the consulting service required in the CON Standards.

There are other specific revisions that should be considered. For example, the requirement to have specific support services on-site may be unreasonable. Due to space considerations at many medical centers, certain support and ambulatory services have been moved out of the main hospital facility. Hence, the requirements for on-site availability of various laboratory, pathology and blood services, and support services, like radiation therapy, should be required to be available on-site, or *immediately adjacent to the proposed hospital site*.

Other specific citations need to be corrected. The Pediatric Oncology Group (POG) and the Children’s Cancer Group (CCG) cited in Section 3 no longer exist. These organizations have combined to form the Children’s Oncology Group (COG). Additionally, the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) is now called the Foundation for the Accreditation of Cellular Therapy (FACT). Furthermore, as noted previously, FACT and JACIE have combined their efforts to provide minimum guidelines for facilities and individuals performing hematopoietic stem cell transplantation and support services. Designations of these organizations should be changed in the next version of the CON Review Standards.

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for BMT, and we urge that the CON Commission initiate a process to revise these Standards as soon as is possible. We will be pleased to participate in this process as appropriate.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert A. Meeker". The signature is fluid and cursive, with the first name "Robert" being the most prominent part.

Robert A. Meeker
Strategic Program Manager